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SUBJECT: CHINESE MALARIAL RESEARCH IN MADAGASCAR AND  
COMOROS

REF: 08 ANTANANARIVO 0628

¶1. (U) Summary: Chinese researchers have targeted several small islands: Nosy Be, Madagascar and Moheli, Comoros, to conduct drug trials of a new treatment with the hopes of eradicating malaria. Because malaria is among the top three causes of death and disease, especially among young children, and the disease affects the productivity and thereby economic growth of Malagasy and Comoran families, new measures to control the disease are embraced. However, infectious disease experts are concerned about potential human rights or ethical violations in addition to population health concerns. In an effort to provide technical guidance, the GOM permitted the local research institution, Institut Pasteur, and the Roll Back Malaria team (including one USG malaria advisor from the Center for Disease Control and Prevention (CDC)) to negotiate the details of the study with members of the research team from Ghangzou University of Traditional Chinese Medicine (GUTCM). End summary.

#### Malaria in Madagascar

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¶2. (U) Madagascar is a malaria endemic country with as much as 90% of the population exposed to permanent or seasonal malaria transmission, becoming infected multiple times throughout the year. In 2005, the Ministry of Health (MOH) recorded over 2 million cases of malaria, nearly one-fifth of which ended in death. Recent data show a reduction in malaria cases; malaria has fallen to the 2nd or 3rd disease most frequently diagnosed during consultations at hospitals or health centers. While the incidence of malaria has decreased over the past couple of years due to improved coverage of malaria interventions, the disease persists and it is still the leading cause of death among children under five years of age.

¶3. (U) The United Nations Secretary General Ban Ki-Moon called for universal coverage of all malaria interventions which include the use of long-lasting insecticide treated nets (LLIN), routine indoor residual spraying (IRS), intermittent preventive treatment during pregnancy (IPTp), rapid diagnostic tests (RDT), and prompt treatment using antimalarial drugs. Madagascar receives funding, technical support, and the aforementioned health commodities from the Global Fund to fight AIDS, TB, and Malaria (GFATM) and the USG Presidential Malaria Initiative (PMI) to conduct a variety of intervention strategies tailored to the incidence of malaria and environmental causes.

#### Mass Drug Administration

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¶4. (U) The Government of Madagascar (GOM) recognizes the threat of malaria in its own ambitious Madagascar Action Plan, which outlines development goals for the country. Through decreasing the number of cases and deaths due to malaria, the GOM hopes to work towards its elimination. In fact, malaria was eradicated from 1949 to 1959 through treating children with chloroquine and killing mosquitoes with DDT. At present, traditional ways to eradicate malaria

focus on using LLINs to protect humans from being bitten or by using IRS to kill mosquitoes.

15. (U) Li Guoqiang, a pharmaceutical researcher from the GUTCM, is looking at it differently. He aims to eradicate the malaria parasite from humans by doing mass drug administration (treating all individuals, not just those who are infected) with Artequick), a pill that contains both the World Health Organization (WHO)-recommended Artemisinin Combination Treatment (ACT) and primaquine. In fact, most malaria infections are asymptomatic, thereby often going untreated. When a mosquito bites a human who is a carrier of the malaria parasite, the mosquito becomes infected and can then transmit malaria to someone else. Thus, the hypothesis of mass drug administration (MDA) - if all humans in a contained area, such as an island, are treated with antimalarials, then the parasite source, humans, may cease to be carriers.

16. (U) MDA has been attempted since the 1920s and each time has led to a decrease in the prevalence of the parasite in human blood as well as a reduction in the number of people infected with malaria. Not only is it difficult to deliver MDA but there are concerns that such widespread use could lead to drug resistance. None of the trials have resulted in complete interruption of malaria transmission, except for one case. In 1996, the people of Aneityum, Vanuatu completed eight rounds of MDA in addition to continued use of ITNs and other environmental controls; this led to the elimination of malaria from the small island found in the South Pacific Ocean. A major challenge of MDA is that anyone entering the area has the potential to spoil the 100% malaria-free zone, thereby making control and surveillance vital to the success and sustainability of such an endeavor. The population of Aneityum has remained malaria free, in part, some say, to the ongoing malaria monitoring efforts.

#### Chinese Study Comes to Madagascar

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17. (U) GUTCM, located in southern China, was founded in 1956 and continues to be governed by the state. As one of the four oldest colleges of its kind, its reputation as a research base in the field of Clinical Pharmacology, authorized by the Chinese Ministry of Public Health, is growing. Recently, GUTCM has conducted several studies delivering MDA (Artequick), seeing success in two remote areas of Cambodia as well as its most recent trial in the Comoros. In the Comoros in 2008, nearly 50% of the people on the island of Moheli were carriers of the parasite; the most common cause of death for children under the age of 5 was malaria. The MDA to Moheli, 40,000 residents resulted in reducing malaria cases from 23% to 1.4% within the first two months of treatment. However, inadequate regulation and lack of treatment plans in place for the fishermen and traders that frequently travel between the Comoran islands threaten the sustainable impact of this MDA trial.

18. (U) In Madagascar, China's development programs also focus on combating malaria (reftel). GUTCM's Principal Investigator Jian-Ping Song aims to use similar methodology in Madagascar as in Comoros by delivering MDA during a 2-year pilot study in Nosy Be, a small island 15 kilometers off the northwest coast of Madagascar. The Nosy Be district hospital measured an average of 17,492 cases of malaria per year, affecting nearly 1 in 3 residents. The study population will include all Nosy Be residents (population near 49,000) over six months of age. In addition, sentinel surveillance sites will be included at the airport and port to ensure that all people entering Nosy Be are receiving treatment. Researchers intend to establish a Malaria Control Center to train community health volunteers, manage and analyze data, and develop a reporting system; supply all study sites with laboratory centers complete with diagnostic microscopic equipment and at least one to two lab technicians; train community health volunteers, one or two per 300 residents, to supervise medication administration with 100% coverage; and provide free diagnostic and malaria treatment services.

## Human Rights and Ethics

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¶9. (U) Made up of doctors, researchers, and public health experts from the USG Center for Disease Control and Prevention (CDC), the World Health Organization (WHO), UNICEF, and the World Bank, the Roll Back Malaria (RBM) technical working group found several human rights and ethical issues of concern regarding the research protocol. First, bioethics measures include informed consent (willingness to participate, knowledge of study, information at the appropriate literacy level). The success of MDA is dependent on most of the residents taking part in the study without coercion and with an explanation of all potential benefits and risks. Second, there are drug safety concerns with the inclusion of pregnant women and children less than six months of age, something the GUTCM team is pressing. Safety and effectiveness of some antimalarial drugs have not been established for children and pregnant women, and there are contra-indications in children for primaquine, one of the components of Artequick). Third, the study includes the cessation of ALL other prevention and control measures (LLINs, IRS, etc.) which, at its conclusion, would still be helpful in retaining sustainable morbidity reduction. Especially as Nosy Be is a prime domestic and international tourist destination with one international airport and one maritime port, there is heavy traffic flow in and out of the island and a re-emergence of malaria is plausible without ongoing control measures. Finally, with mass treatment there is the possibility of developing drug resistance. Inadequate dosing, incomplete course of therapy, and inappropriate drug use contribute to the emergence and spread of drug resistant-parasites. This already occurred with respect to the former malaria treatment widely used in Madagascar, chloroquine, for which parasites have developed a high level of resistance (40%).

Comment

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¶10. (U) As seen in other pilot studies, specifically in Vanuatu and possibly the Comoros, MDA has the potential to eradicate malaria in small, remote island nations. Nosy Be, a tourist hot spot, is not as isolated as the former two examples. The biggest threat to the success of MDA in Madagascar is controlling malaria from being reintroduced in Nosy Be, hardly an easy feat considering that a large number of tourists come from Madagascar, currently a breeding ground for malaria. Though infectious disease experts do not recommend this as a malaria prevention and control strategy in Madagascar at this time, the GOM has agreed to proceed as a result of political pressure. With certain control measures recommended by the international malaria experts making up the Roll Back Malaria team, the primary human rights and ethical concerns will be raised and hopefully, abated. End comment.

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